

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA**

IN RE INCRETIN-BASED
THERAPIES PRODUCTS LIABILITY
LITIGATION

Case No. 13-md-2452-AJB-MDD
As to all related and member cases

**ORDER GOVERNING THE
PRODUCTION OF
ELECTRONICALLY STORED
INFORMATION**

This order relates to the production of documents and supplements all other discovery rules and orders as between defendants Merck Sharp & Dohme (“Merck”) and Novo Nordisk Inc. (“Novo”), collectively “Defendants,” and all plaintiffs in this litigation. It streamlines Electronically Stored Information (“ESI”) production to promote a “just, speedy, and inexpensive determination” of this action, as required by the Federal Rules of Civil Procedure.

A. Already-Produced Documents

On April 24, 2013, Merck produced the New Drug Application (“NDA”) and Investigational New Drug (“IND”) Application files for Januvia and Janumet, as collected on December 11, 2012. On April 24, 2013, Merck also produced the FDA-approved package inserts for Januvia and Janumet. Together, this production included

1 359,089 pages. Nothing in this order requires Merck to amend, alter, or re-do its
2 production of these materials.

3 B. Format of Production

4 1. The Parties shall produce electronic documents in a single-paged Tagged
5 Image File format (“TIFF”) with extracted text with an accompanying load file to
6 indicate the location and unitization of the TIFF files. The Parties will also produce
7 hard copy documents in single-paged Tagged Image File format (“TIFF”).

8 2. Each page of a produced document shall have a legible, unique page
9 identifier (“Bates Number”), and confidentiality legend (where applicable), on the
10 face of the image at a location that does not interfere with the information from the
11 source document.

12 3. To the extent possible, Defendants will provide the following metadata
13 fields:

- 14 a) Beginning bates number
- 15 b) Ending bates number
- 16 c) Beginning attachment number
- 17 d) Ending attachment number
- 18 e) Attachment count (email)
- 19 f) Attachment name (email)
- 20 g) Custodian/Source
- 21 h) Author/From
- 22 i) Document type
- 23 j) Subject
- 24 k) Recipient
- 25 l) CC
- 26 m) BCC
- 27 n) Sent date
- 28 o) Received date

- p) Create date
- q) Last modified date
- r) DocExt
- s) File name
- t) File path
- u) Native file link
- v) Text path
- w) Importance
- x) File size
- y) Page count
- z) Redacted

This list of fields does not create any obligation to create or manually code fields that are not automatically generated by the processing of the ESI, that do not exist as part of the original metadata of the document, or that would be burdensome or costly to obtain. The Custodian/Source metadata field shall be provided for all documents produced.

4. In scanning paper documents, distinct documents shall not be merged into a single record, and single documents shall not be split into multiple records (*i.e.*, paper documents should be logically unitized). Parent-child relationships (the association between an attachment and its parent document) shall be preserved. Original document orientation shall be maintained (*i.e.*, portrait to portrait and landscape to landscape).

5. Excel spreadsheets that do not require redaction shall be produced natively. PowerPoint presentations that do not require redaction may be produced natively or in TIFF. Any document produced natively will have a corresponding place holder TIFF image for these records bearing the legend "This document produced in native file format only." Prior to the production of native documents, the Parties will reach

1 agreement on the format and use of such native documents. Other document formats
2 that present imaging problems shall promptly be identified, and the Parties shall meet
3 and confer to attempt to resolve the problems.

4 6. The mere production of ESI in this litigation as part of a larger production
5 shall not itself constitute a waiver for any purpose.

6 7. Pursuant to Federal Rule of Evidence 502(d) and the governing Protective
7 Order in this case, the inadvertent production of a privileged or work product
8 protected document is not a waiver in the pending case or in any other federal or state
9 proceeding.

10 8. The Parties are not required to produce exact duplicates of electronic
11 documents stored in different locations. Defendants may globally de-duplicate
12 identical ESI, which will be determined as follows:

13 (i) Electronic files will be de-duplicated based upon calculated MD5 Hash
14 values for binary file content. File contents only will be used for MD5 Hash
15 value calculation and will not include operating system metadata (filename, file
16 dates) values.

17 (ii) Messaging files will be de-duplicated based upon MD5 Hash values for the
18 message family, including parent object and attachments. The following fields
19 will be used to create the unique value for each message: To; From; CC; BCC;
20 Date Sent; Subject; Body; and, attachment count. Messaging materials will be
21 de-duplicated at a family level, including message and attachment(s).

22 If Defendants de-duplicate identical ESI, Defendants shall provide custodian
23 associations in a semi-colon delimited overlay file that includes duplicate custodian
24 name information and related source file paths for the duplicate custodians. The
25 overlay files shall be produced after every production and shall be regularly updated
26 to account for rolling productions. The parties shall produce documents on CD, DVD,
27 or hard drives.

9. No party has an obligation to make its production text-searchable; however, if a party's documents exist in text-searchable format, then such documents shall be produced in the same text-searchable format at no cost to the receiving party.

10. For each document containing searchable text, a single text file shall be provided along with the image files and metadata. The text file name shall be the same as the Bates number of the first page of the document. File names shall not have any special characters or embedded spaces. Electronic text must be extracted directly from the native electronic file unless the document was redacted, an image file, or a hard copy document. Subject to paragraph B.9, in these instances, a text file shall be created using OCR and shall be produced in lieu of extracted text.

11. Absent a showing of good cause, no party need restore any form of media upon which backup data is maintained in a party's normal or allowed processes, including but not limited to backup tapes, disks, SAN, and other form of media, to comply with its discovery obligations in the present case. It will be presumed, although either party may seek to rebut that presumption, that costs for production from a backup or archive, to the extent it is deemed necessary, will be paid by the party making the request.

12. Absent a showing of good cause, non-transcribed voicemails, and PDAs are deemed not reasonably accessible and need not be collected and preserved.

13. When processing ESI, EST shall be selected as the time zone.

14. Objects embedded in Microsoft Word and .RTF files will be extracted as separate documents and produced as attachments to the document.

15. Compression file types (i.e., .CAB, .GZ, .TAR, .Z, .ZIP) shall be decompressed in a reiterative manner to ensure that a zip within a zip is decompressed into the lowest possible compression resulting in individual folders and/or files.

16. Audio files and video files shall be produced in native format with the source file path provided.

1 17. Any documents that are replaced in later productions shall be clearly
2 designated as such, by appending an “ R” to the production prefix. When a party
3 produces a replacement production indicated by “R,” the receiving party must discard
4 or return to the producing party all copies, including working copies, of the original,
5 replaced image.

6 18. Any native files that are produced shall be produced with the source file
7 path provided, as well as all extracted text and applicable metadata fields set forth in
8 this order.

9 19. Documents with dynamic fields for file names, dates, and times will be
10 processed to show the field code (e.g., “[FILENAME]” or “[AUTODATE]”), rather
11 than the values for such fields existing at the time the file is processed.

12 20. The Parties will meet and confer, as necessary, regarding potentially
13 relevant structured data sources.

14 C. Production of Custodial Files

15 1. Upon agreement of the parties, Merck and Novo each shall identify up to
16 eight custodians, keeping in view the pleaded claims and defenses in this litigation, to
17 Plaintiffs’ counsel. Defendants shall begin producing responsive, non-privileged,
18 reasonably accessible documents, on a rolling basis, from the custodial files of these
19 custodians. Upon the substantial completion of the production of these custodial files,
20 the Parties shall meet and confer concerning the production of additional custodial
21 files. This paragraph does not relieve the Defendants from their obligation to produce
22 documents otherwise responsive to Plaintiff’s production requests made in, or
23 applicable to, this MDL, subject to Defendants’ objections and meet and confers
24 between the parties.

25 2. Merck and Novo will use search terms, to be agreed to by the parties, to cull
26 collected electronic data from 1999 to June 1, 2013. Defendants will notify Plaintiffs
27 when the production of a custodial file is substantially complete. Upon substantial
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1 completion of the production of the custodial files of the above-referenced custodians,
2 the parties will meet and confer regarding the production of additional custodial files,
3 if any. As necessary, the parties will meet and confer with respect to the process by
4 which supplemental custodial file productions will be made, subject to agreement of
5 the parties.

6 3. If Plaintiffs elect to take the deposition of a custodian prior to receiving
7 notice that the production of the custodian's documents is substantially complete,
8 Plaintiffs will not be entitled to further depose that witness on the grounds that the
9 document production was not complete.

10 4. This order supersedes all pending or previously served instructions pursuant
11 to Requests for Production directed to Defendants, and governs all pending or future
12 instructions accompanying Requests for Production, Requests for Admission,
13 Interrogatories, and deposition notices directed to Defendants.

14 D. Technical Specifications

15 1. All TIFF-formatted documents will be single page, Group 4 TIFF at 300 x
16 300 dpi resolution and 8.5 x 11 inch page size, except for documents that in the
17 producing party's reasonable judgment require a different resolution or page size. If a
18 color image is produced in black and white, the receiving party may request the
19 producing party to produce the original, color image. After receiving such a request
20 for color production, the parties will meet and confer on a reasonable and cost-
21 effective means of providing the requested documents.

22 2. There will be two Load/Unitization files accompanying all productions. One
23 will be the Image load file and the other will be the Metadata load file.

24 3. Specifications for the image load files will be the following:

25 (i) Every Document referenced in a production image load file shall have all
26 corresponding images, text, and data logically grouped together in a
27 directory structure with a common key to properly load the data.

(ii) Documents shall be produced in only one image load file throughout the productions, unless that document is noted as being a replacement document in the Replacement field of the data load file.

(iii) The name of the image load file shall mirror the name of the delivery volume, and should have an .lfp, .opt or .dii* extension (e.g., ABC001.lfp). The volume names shall be consecutive (i.e., ABC001, ABC002, et. seq.). If a .dii file is produced, the accompanying metadata load file shall be separate from the .dii file and not contained within the .dii file.

(iv) The load file shall contain one row per TIFF image.

(v) Every image in the delivery volume shall be contained in the image load file.

(vi) The image key shall be named the same as the Bates number of the page. Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.), i.e., a separate volume shall be created for each piece of media delivered.

4. Specifications for the metadata load files will be the following:

(i) The metadata load file shall use the following delimiters:

- Column Delimiter: Pipe - | (ASCII 124) or (ASCII 020)
- Text Qualifier: Caret - ^ (ASCII 94) or  (ASCII 254)
- New line: Registered sign - ® (ASCII 174)
- Example: PRODBEGPRODENDPRODBEGATT

(ii) Data for documents shall be produced in only one data load file throughout the productions, unless that document is noted as being a replacement document in the Replacement field of the data load file.

(iii) The first record shall contain the field names in the order of the data set forth in the Metadata.

(iv) All date fields shall be produced in “mm/dd/yyyy hh:mm:ss AM” format.

(v) A carriage-return line-feed shall be used to indicate the start of the next record.

(vi) Load files shall not span across media (e.g., CDs, DVDs, Hard Drives, etc.); a separate volume shall be created for each piece of media delivered.

(vii) The name of the metadata load file shall mirror the name of the delivery volume, and shall have a .dat, .csv or .txt extension (i.e., ABC001.dat).

(viii) The volume names shall be consecutive for each produced source. (i.e., ABC001, ABC002, et. seq.).

E. Costs

While each party expressly reserves its rights to seek costs relating to this litigation, including the costs of producing documents, initially each party will bear the costs to process and review its own documents and readily accessible ESI. To the extent any party requests data that is not readily accessible, subject to Paragraph C.11, the parties shall comply with the Federal Rules of Civil Procedure in determining whether the inaccessible data is to be produced, including the costs to process or review unique or non-standard data. The parties shall confer concerning inaccessible material, including inaccessible ESI, prior to seeking the Court’s assistance.

F. Protective Order

All documents that have been or will be produced by the parties will be subject to the terms of the Protective Order entered in this litigation.

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1 G. Predictive Coding

2 The parties agree that Defendants may, but are not required to, use predictive
3 coding in connection with the review of documents in this litigation.

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5 IT IS SO ORDERED.

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7 DATED: November 15, 2013


8 Honorable Mitchell D. Dembin
9 United States Magistrate Judge
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